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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,868	DECKMYN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/02&6/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 65-82 are pending and under examination.

2. Applicant's election with traverse of Group I, claims 44-54 and 63-64 (now claims 65-82) drawn to a cell line being able to produce a monoclonal antibody comprising a Fab fragment, the cell line being one of the cell line deposited under accession number LMBP 5108CB or a cell line producing a monoclonal antibody having a reactivity identical to that of a monoclonal antibody obtained from the cell line LMBP 5108CB antibody and a composition thereof. filed on 9/30/04, is acknowledged.

3. Applicant's IDS, filed 2/11/02 and 6/4/02, is acknowledged, however, the references filed on 2/11/02 were crossed out as they were duplicates of the references filed 6/04/02.

4. The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. Page 27, lines 21-25, page 28, lines 14-15, has described primer sequences, which must have a sequence identifier. Correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 65-71, 75 and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The "monoclonal antibody" recited in claims 71 and 75 has no antecedent basis in base claims 65 and 72, respectively. Base claims 65 and 72 only recite a monovalent antibody fragment.

B. Claim 82 is indefinite in the recitation that "a humanized antibody fragment derivable from the cell line". It is well known that an antibody fragment is derived from an intact antibody not a cell line. It is unclear how a humanized antibody would be derived from a cell line.

C. Claim 65 is seen to be improper, since it is drawn to a composition, but recites a single component. In chemistry, compositions requisitely contain two or more components. The instant claim 65 fails to provide two or more components. The recitation of a single component containing composition renders claim 65 indefinite.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 65-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The phrases:

A. "monovalent antibody fragment" claimed in claim 65, line 1 and claim 72, line 1;
B.
C. "single variable domain" claimed in claims 66 and 73;
D. "inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions" claimed in claim 74;
E. "at least 60% sequence identity with SEQ ID NO:1/2/3/4" claimed in claims 67-70 and 76-79

represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 9/30/04 does not point to the specification for support for the newly added limitations "monovalent antibody fragment" as claimed in claim 65, line 1 and claim 72, line 1; "single variable domain" as claimed in claims 66 and 73, "inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions" claimed in claim 74 and "at least 60% sequence identity with SEQ ID NO:1/2/3/4" as claimed in claims 67-70 and 76-79. However, the specification does not provide a clear support for such limitations. It is noted that the specification on page 21 line 11, only discloses the monovalent 6B4 Fab fragments. Further, the specification on page 26, lines23-26 discloses the *ex vivo* ristocetin-induced platelet aggregation. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

9. Claims 65-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridoma LMBP 5108CB, recited in claims 71, 75, and 80-82, that produce the 6B4 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the

hybridoma has been deposited under the Budapest Treaty and that the hybridoma will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample *or for the enforceable life of the patent whichever is longer*. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Further, amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required as set forth in 37 C.F.R. 1.809(d).

Further, the specification does not reasonably provide enablement for a pharmaceutical composition or a monovalent antibody fragment which binds in vivo to human platelet glycoprotein GPIb in claim 65 comprising a variable region encoded by a sequence comprising any "sequence having at lest 60% sequence identity" with SEQ ID NO: 1/2 in claim 67-68 and 76-77, or a monovalent antibody fragment which inhibits platelet adhesion and/or inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions in claim 74 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Besides the anti-GPIbα glycoprotein (see page 16, lines 32-33), the specification fails to provide guidance as to what anti-GPIb- would lead to inhibition of platelet adhesion and/or inhibition of platelet activation under high shear conditions and/or inhibition of platelet aggregation under high shear conditions.

There is insufficient guidance and direction as to make and use the claimed antibodies and fragments thereof, wherein the variable region is encoded by a sequence comprising a sequence having at least 60% sequence identity with SEQ ID NO: 1 or 2 or having at least 60% sequence identity with SEQ ID NO:3 or 4.

It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of

framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that variable region of the monovalent antibody fragment as defined by the claims which may contain less than the full complement of CDRs from the heavy and light chain variable regions of an GPIb antibody have the required binding function. The specification provides no direction or guidance regarding how to produce monovalent antibody fragments comprising a sequence having at least 60% sequence identity as broadly defined by the claims. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone. Panka et al (Proc Natl Acad Sci USA Vol 85 3080-3084 5/88) demonstrate that a single amino acid substiution of serine for alanine results in decreased affinity. In at least one case it is well known that an amino acid residue in the framework region is involved in antigen binding (Amit et al Science Vol 233 747-753 1986).

The specification fails to provide guidance regarding the inhibition of platelet activation in vivo, yet claiming such functional activity. Further the specification discloses the *ex vivo* ristocetin-induced platelet aggregation, yet claiming an *in vivo* inhibition of platelet activation.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims 65-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody which binds in vivo to human platelet glycoprotein GPIbα without incurring thrombocytopenia, a fab fragment and a pharmaceutical composition thereof, a fragment comprising the variable region VL of SEQ ID NO:3 encoded by SEQ ID NO:1 and the variable region VH of SEQ ID NO: 4 encoded by SEQ ID NO:2, the monoclonal antibody produced by the hybridoma LMBP 5108CB, and a Fab fragment thereof, a cel line capapble of producing an antibody directed against GPIb which has the accession number LMPB 5108CB.

Applicant is not in possession of a pharmaceutical composition or a monovalent antibody fragment which binds in vivo to human platelet glycoprotein GPIb in claim 65 comprising a

variable region encoded by a sequence comprising any "sequence having at lest 60% sequence identity" with SEQ ID NO: 1/2 in claim 67-68 and 76-77, or a monovalent antibody fragment which inhibits platelet adhesion and/or inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions in claim 74.

Applicant has disclosed only SEQ ID NOs: 1-4; therefore, the skilled artisan cannot envision all the contemplated nucleic/amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 65-70, 72-74 and 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Pat. No. 5,455,030.

The `030 patent teaches a 215 amino acid sequence having 73% sequence identity with SEQ ID NO:3 encoded by a 448 nucleic acid sequence comprising a sequence having 66% sequence identity with SEQ ID NO: 1 (see Fig 22, and attached sequence alignment in particular). The `030 patent teaches that the nucleotide sequence and translation of the sequence for the heavy chain of a mouse anti-bovine growth hormone (BGH) monoclonal antibody (see col., 5, lines 34-36 in particular). Further, the `030 patent teaches a 242 amino acid sequence having 83% sequence identity with SEQ ID NO:4 encoded by a 706 nucleic acid sequence comprising a sequence having 78% sequence identity with SEQ ID NO: 2 (see Fig 40, and attached sequence alignment in particular). The `030 patent teaches that anti-fluorescein monoclonal antibodies with the sequences shown in Figure 40 (see Figure 40, and example 9, in particular). The `030 patent further teaches that a single polypeptide chain binding molecule which has binding specificity substantially similar to the binding specificity of the light and heavy chain aggregate variable region of an antibody (see col., 3, lines 5-10 in particular). The `030 patent teaches that the use for the binding proteins, including uses in diagnostic, therapy, in vivo and in vitro imaging (see col., 3, lines 17-20 in particular). Finally, the `030 patent teaches the therapeutic uses and compositions of the single chain binding protein can be utilized (see col., 11 lines 7-11 in particular).

The terms "comprising" and "having" in instant claims 67-70 and 76-79 are open ended. They would open up the claims to include the reference nucleic/amino acid sequences.

While the prior art teachings may be silent as to the "binds in vivo to human platelet glycoprotein GPIb without incurring thrombocytopenia", "prevents the binding of von Willebrand factor to human platelet glycoprotein GPIb", "which inhibits platelet adhesion and/or inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions" per se; the product in the reference is the same as the claimed product. Therefore these limitations are considered inherent properties.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not bind to the GPIb recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 65-70, 72-74 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward *et al* (1995) (IDS Ref. No. C4), in view of in view of Owens *et al* (1994) and U.S. Pat. No. 4,731,245.

Ward *et al* teach 17 monoclonal antibodies that bind GPIbα epitope of the platelet surface glycoprotein (see table 1 in particular). Ward et al teach that eight antibodies mapped to the N-terminal fragments of gpIba, and these were tested for their ability to block binding of 125I-labelled von Willebrand factor to washed platelets in the presence of ristocetin or botrocetin. Ward et al teach that mAb P014 (epitope 1-282), P024 (epitope 1-282), P073 (epitope 1-282), P074 (epitope 1-282) and P077 (epitope 1-282) completely inhibited vWF binding with wither modulator (see page 1337, 1st col., 3rd paragraph and table I in particular). Finally, Ward et al teach that the inhibitory functions of the CD42b antibodies with their epitopes on gpIba may provide valuable insights into mechanisms of vWF function both in vitro and in vivo (pg 1337, last paragraph in particular).

The claimed invention differs from the reference teaching only by the recitation of a composition comprising a monovalent antibody fragment in claim 65.

Owens *et al* teach the modification of murine antibodies such as a single chain antibody, a Fab fragment or a humanized antibody using monoclonal antibody technology. Owens *et al* further teach humanized antibodies use in therapy of human diseases or disorders, since the human or humanized antibodies are much less likely to induce an immune response. Also, antibody fragments are the reagents of choice for some clinical applications (see the entire document).

The `245 patent teaches a composition comprising the antibody to the PLS antigen, as the active ingredient in association with a pharmaceutically acceptable carrier or excipient. The composition may preferably take the forms suitable for oral administration. Advantageously, the composition may be formulated in dosage unit form. The amount of the active ingredient contained in each dosage unit may be adjusted so as to enable the administration of the antibody at a daily dose (see col., 7 line 63 through col., 8 line 3 in particular).

Claims 67-70 and 76-79 are included because the resultant monovalent fragment would contain a variable region encoded by a sequence comprising a sequence having at least 60% sequence

identity with SEQ ID NO:1 or 3 and it would comprise a sequence having at least 60% sequence identity with SEQ ID NO: 2 or 4.

While the prior art teachings may be silent as to the "without incurring thrombocytopenia", "which inhibits platelet adhesion and/or inhibits platelet activation under high shear conditions and/or inhibits platelet aggregation under high shear conditions" per se; the product in the reference is the same as the claimed product. Therefore these limitations are considered inherent properties.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce the monoclonal antibody taught by Ward et al as Fab as taught by the Owens *et al* and place the resultant Fab fragment which binds to platlete glycoprotein GPIbα polypeptide taught by the Ward et al reference in a composition taught by the '245 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because eight antibodies mapped to the N-terminal fragments of gpIba, and these were tested for their ability to block binding of ^{125}I-labelled von Willebrand factor to washed platelets in the presence of ristocetin or botrocetin and because it would further lead to insights into mechanisms of vWF function both in vitro and in vivo. Given that the antibody fragments are the reagents of choice for some clinical applications one ordinary skill in the art at the time the invention was made would be motivated to include such fragments in a composition because the composition can be formulated in dosage unit form. The amount of the active ingredient contained in each dosage unit may be adjusted so as to enable the administration of the antibody at a daily dose as taught by `245 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 29, 2004

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